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Increasing organ donation via anticipated regret: the INORDAR project

Submission date
23/11/2011

Recruitment status
No longer recruiting

Registration date
19/12/2011

Overall study status
Completed

Last Edited
16/06/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

There is an insufficient supply of donor organs to meet the demand for organ transplantations worldwide. The NHS Blood and Transplant (NHSBT) Annual Report 2009-2010 found that 90% of the UK general public approve of organ donation. Despite this, only 30% of people in the UK (37% in Scotland) have registered as posthumous organ donors. The 2011 Nuffield Council on Bioethics suggested that registration may be increased if people received financial incentives, such as the NHS paying for their funeral. Although such incentives may encourage people to register, the key to drastically increasing registration is to identify and overcome the psychological barriers that prevent organ donation and to determine what can promote organ donor registration.

The Theory of Planned Behaviour (TPB) suggests that people are likely to register as an organ donor when they have a positive view of registration, believe that they are able to achieve this and think that friends and family support registration. However, research in the USA and the UK suggests that emotions and attitudes are stronger predictors of organ donor registration than traditional TPB variables. These can include feeling disgust towards organ donation and believing that registration will harm the registrant. This suggests that donor registration interventions should target the emotions that guide decision making. We plan to focus on the emotion of regret.

Regret is an emotion that is experienced when people believe that they should have acted differently. It is possible to anticipate the amount of regret that one would feel if they did not perform an action. The desire to avoid this emotion motivates people to undertake an action when they anticipate feeling regret for not acting. Anticipated regret therefore binds people to actions by signalling the emotional consequences of inaction.

In two initial studies, it was found that people had greater intentions to register as an organ donor after being asked whether they would later regret not registering than the control arm (not being asked whether they would later have regrets). These studies demonstrate that anticipated regret increases peoples intentions to register as an organ donor. However, people do not always act upon their intentions. In a further study it was found that anticipated regret increased people's self-reported registration as an organ donor. The aim of the study is to test whether asking people whether they would later regret not registering as an organ donor increases registration.

Who can participate?
A large, nationally representative sample of the adult Scottish general public will be recruited via post. Participants will be randomly selected from a list containing 1.2 million members of the adult Scottish general public and invited to complete and return a brief questionnaire. Participants will be 18 years or older and will not be registered organ donors.

What does the study involve?
The materials that the participant receives depend on which of the four groups they have been randomly allocated into. The no questionnaire control group (NQC) simply receive a letter and donor registration form. The questionnaire control (QC) group receive a questionnaire measuring their emotions and attitudes towards organ donation. Non-donors also rate their intentions to register as a donor. The attitudes questionnaire (AQ) group receive these questions, plus items assessing attitudes, perceived control, and subjective norms. The anticipated regret (AR) group complete all of these questions, plus two additional items assessing whether they would later regret not registering as a donor. NHSBT-verified organ donor registration is measured 6 months after our postal intervention: NHSBT search the Organ Donor Register to determine whether the participant has become a registered organ donor and, if applicable, when they registered.

What are the potential benefits and risks of participating?
Distributing donor registration forms is likely to increase the population's supply of posthumous organ donors. This may benefit any participants (or their loved ones) who may need an organ in the future. This study may also benefit participants by evoking the positive feelings associated with organ donor registration. Finally, receiving the form may stimulate people who have been considering registration to take that step. No risks are anticipated.

Where is study run from?
University of Stirling (UK)

When is the study starting and how long is it expected to run for?
January 2012 to December 2012

Who is funding the study?
Chief Scientist Office of the Scottish Executive Health Department (UK)

Who is the main contact?
Prof. Ronan E OCarroll
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Study website
http://www.stir.ac.uk/natural-sciences/research/groups/psychology/chbc/inordar/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZH/4/686

Study information

Scientific Title
A randomised controlled trial to test if a simple anticipated regret manipulation leads to a significant increase in organ donor registrations

Acronym
INORDAR

Study objectives
The aim of this study is to test whether a large scale, simple anticipated regret manipulation leads to a significant increase in NHS Blood and Transplant (NHSBT) verified organ donor registrations. If it is found that the intervention is successful, the trialists will determine whether this effect is due to people having greater intentions to register and less negative emotions and attitudes towards registration.

Research questions:
1. Does a brief, theory-based anticipated regret intervention lead to a significant increase in organ donor registrations?
2. If we do observe an anticipated regret effect, what is the mechanism, e.g. is it fully mediated via intentions and/or negative emotions and attitudes?
3. What effect size is observed, to inform the power calculation for the next stage, a UK wide translational study?
4. What is the feasibility, response rate etc. to guide such a study?

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee, 15/12/2011, ref: 11/SS/0093

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request an information sheet

Health condition(s) or problem(s) studied
Regret

Interventions
The study will have four arms:
1. No-questionnaire control (NQC)
2. Questionnaire control (QC)
3. Attitude questionnaire (AQ)
4. Anticipated regret (AR)

The postal survey that the participants receive varies between these arms.

NQC:
We are including this arm to see whether simply being contacted increases organ donor registration. This arm will simply receive a letter and a donor registration form. They will also complete some demographic questions.

QC:
This arm will receive the same materials as the NQC arm, plus an additional questionnaire assessing their emotions and attitudes towards organ donation. This questionnaire will measure the "ick" and "jinx" factors, medical mistrust, bodily integrity and perceived benefit. The "ick" factor will be measured using three items (e.g. The thought of organ donation makes me uncomfortable). Three "jinx" items will be rated (e.g. The surest way to bring about my own death is to make plans for it by signing an organ donor card). Two items will measure bodily integrity (e.g. The body should be kept whole for burial). There will be four medical mistrust items (e.g. If I sign an organ donor card, doctors may not try so hard to save my life). Perceived benefit will be measured with four items (e.g. Organ donation helps to bring meaning to the death of a loved one). All these items will be rated on a 7-point Likert scale (1 = strongly disagree, 7 = strongly agree). Non-donors will also be asked to complete two questions measuring their intentions to register as an organ donor in the future (e.g. I will definitely register as an organ donor in the next month; 1 = strongly disagree, 7 = strongly agree). We will also include filler questions to ensure that the number of items in this arm is identical to the AQ and AR arms.

AQ:
The AQ arm will receive the same materials as the QC arm, plus additional items measuring attitudes, perceived control, and subjective norms. The attitudes, perceived control and subjective norm indices will only be completed by non-donors. Attitudes will be measured with two items (e.g. I support the idea of organ donation for transplant purposes). Two subjective norm items will be included (e.g. Most people who are important to me think that I should register as an organ donor in the next month). The attitudes and subjective norm items will be rated on 7-point Likert scales (1 = strongly disagree, 7 = strongly agree). Three items will measure perceived control (e.g. How much control do you have over registering as an organ donor in the next month?; 1 = no control, 7 = complete control). Once again, non-donors will also be asked to rate their intentions to register as a donor, using the items described above. We will also include filler questions to ensure that the number of items in this arm is identical to that of the QC and AR arms.

AR:
Non-donors in this arm will complete the same indices are the AQ arm, plus two items measuring anticipated regret: If I did not register as an organ donor in the next month I would feel regret (1 = definitely no, 7 = definitely yes) and If I did not register as an organ donor in the next month, I would later wish I had (1 = strongly disagree, 7 = strongly agree).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Verified number of NHS Blood and Transplant organ donor registrations in each of the four study arms, 6 months after receiving the postal questionnaire
2. NHS Blood and Transplant will search the Organ Donor Database to see whether participants have registered as organ donors and, if applicable, when they registered

Secondary outcome measures
1. Intentions to become an organ donor in the future
2. If the anticipated regret intervention is successful the trialists will test whether the increase in registration is due to people having greater intentions to register as an organ donor and less negative emotions and attitudes towards donation
3. These variables will be measured in questionnaires using the indices described above

Overall study start date
02/01/2012

Completion date
21/12/2012

Eligibility

Key inclusion criteria

1. Participants will be a large, nationally representative sample Scottish general public
2. Adult (over 18 years of age)
3. Not be registered organ donors when they receive the questionnaire

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The aim is to recruit 2260 participants. After accounting for low response rates and pre-existing registered organ donors, 14,520 questionnaires need to be distributed to obtain this sample size.

Key exclusion criteria
1. Registered organ donors
2. Actively withdraw from study

Date of first enrolment
01/04/2012

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Stirling
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office ref: CZH/4/686

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of results paper in the journal Health Psychology.

Intention to publish date
31/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/03/2012		Yes	No
Results article	results	01/11/2016		Yes	No